Consolidated Financial Results for the Three Months Ended April 30, 2016 [Japanese GAAP]

June 14, 2016

Company name: SanBio Company Limited
Stock exchange listing: Tokyo Stock Exchange
Code number: 4592
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Scheduled date of filing quarterly securities report: June 14, 2016
Scheduled date of commencing dividend payments: —
Availability of supplementary briefing material on quarterly financial results: No
Schedule of quarterly financial results briefing session: No

(Amounts of less than one million yen are rounded down.)

1. Consolidated Financial Results for the Three Months Ended April 30, 2016 (February 1, 2016 to April 30, 2016)

(1) Consolidated Operating Results (% indicates changes from the previous corresponding period.)

	Operating revenue		Operating income		Ordinary income		Net income attributable to owners of parent	
Three months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
April 30, 2016	625	119.7	77	–	(320)	–	(277)	–
April 30, 2015	284	–	(81)	–	(154)	–	(109)	–

(Note) Comprehensive income: Three months ended April 30, 2016: ¥(265) million [–%]
Three months ended April 30, 2015: ¥(107) million [–%]

	Net income per share	Diluted net income per share
Three months ended	Yen	Yen
April 30, 2016	(6.22)	–
April 30, 2015	(2.67)	–

(Note) Diluted net income per share is not stated as net loss per share was recorded although there are potential shares with dilutive effect.

(2) Consolidated Financial Position

	Total assets	Net assets	Equity ratio	Net assets per share
	Million yen	Million yen	%	Yen
As of April 30, 2016	7,660	6,113	79.8	136.74
As of January 31, 2016	8,271	6,366	77.0	142.66

(Reference) Equity: As of April 30, 2016: ¥6,113 million
As of January 31, 2016: ¥6,365 million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended January 31, 2016	–	0.00	–	0.00	0.00
Fiscal year ending January 31, 2017	–				
Fiscal year ending January 31, 2017 (Forecast)		0.00	–	0.00	0.00

(Note) Revision to the forecast for dividends announced most recently: No

3. Consolidated Financial Results Forecast for the Fiscal Year Ending January 31, 2017 (February 1, 2016 to January 31, 2017)

(% indicates changes from the previous corresponding period.)

	Operating revenue		Operating income		Ordinary income		Net income attributable to owners of parent		Net income per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
First half	735	78.9	(1,629)	–	(1,637)	–	(1,543)	–	(34.59)
Full year	886	(24.6)	(3,814)	–	(3,830)	–	(3,641)	–	(81.62)

(Note) Revision to the financial results forecast announced most recently: No

*** Notes:**

(1) Changes in significant subsidiaries during the period under review (changes in specified subsidiaries resulting in changes in scope of consolidation): No

(2) Accounting policies adopted specially for the preparation of quarterly consolidated financial statements: No

(3) Changes in accounting policies, changes in accounting estimates and retrospective restatement
1) Changes in accounting policies due to the revision of accounting standards: No
2) Changes in accounting policies other than 1) above: No
3) Changes in accounting estimates: No
4) Retrospective restatement: No

(4) Total number of issued shares (common shares)
1) Total number of issued shares at the end of the period (including treasury shares):
April 30, 2016: 44,707,491 shares
January 31, 2016: 44,621,741 shares

2) Total number of treasury shares at the end of the period:
April 30, 2016: 16 shares
January 31, 2016: 16 shares

3) Average number of shares during the period:
Three months ended April 30, 2016: 44,632,724 shares
Three months ended April 30, 2015: 40,810,951 shares

* Presentation regarding the implementation status of the quarterly review procedures

These quarterly financial results are outside the scope of quarterly review procedures under the Financial Instruments and Exchange Act. However, at the time of disclosure of these quarterly financial results, review procedures for the quarterly financial statements under the Financial Instruments and Exchange Act have been completed.

* Explanation of the proper use of financial results forecast and other notes

The earnings forecasts and other forward-looking statements herein are based on information available to the Company at the time of preparation and certain assumptions deemed to be reasonable, and the Company does not assure the achievement of any of these. Furthermore, actual results may vary significantly due to various factors. For the assumptions and notes for earnings forecasts, please refer to "1. Qualitative Information on Quarterly Financial Results for the Period under Review, (3) Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information" on page 3 in the attachment.

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1. Qualitative Information on Quarterly Financial Results for the Period under Review

(1) Explanation of Operating Results

The Japanese economy during the first quarter of the fiscal year under review (from February 1, 2016 to April 30, 2016) continued to show a moderate recovery trend, as the employment and income environment remained robust, and capital investment among other business activities indicated signs of a recovery on top of improving corporate earnings. The U.S. economy also continued a moderate recovery trend supported by robust personal consumption, despite the effect of low crude oil prices and other factors.

In the regenerative medicine industry, amid ongoing promotion of the industry in Japan by the enforcement of the Act on the Safety of Regenerative Medicine and the Revised Pharmaceutical Affairs Act in November 2014, a conditional and term-limited approval for sales was granted for the first time in September 2015 under the new program to accelerate the process of regenerative drug approval, for two regenerative medicines developed in Japan. The practical application of regenerative medical products is gradually becoming a reality.

In this environment, the Group (hereinafter referring to both the Company and its consolidated subsidiary, SanBio, Inc. [Mountain View, California, US]) pressed ahead with development, primarily in Japan and the US, for the commercialization of our unique regenerative cell medicine, SB623.

During the first quarter of the fiscal year under review, the Group initiated the enrollment of patients in a Phase 2B clinical trial (156 subjects) of SB623 for the treatment of chronic motor disability resulting from ischemic stroke, starting with two subjects in the US. Currently, the Group continues to recruit additional patients. With regard to the Phase 2 clinical trial of SB623 for the treatment of chronic motor disability resulting from traumatic brain injury (52 subjects), the Group began recruitment of patients in October 2015 in the US, in preparation for patient enrollment.

In Japan, we have been preparing for the conduct of a clinical trial of SB623 for the treatment of traumatic brain injury since July 2015. On March 7, 2016, we submitted a clinical trial notification to the Pharmaceuticals and Medical Devices Agency (PMDA) to expand the ongoing Phase 2 clinical trial of SB623 for traumatic brain injury to Japan. Following a 30-day review period, it is considered approved. As such, the US-based Phase 2 clinical trial for the treatment of traumatic brain injury (52 subjects) became a global trial and to include participating centers from Japan.

As a result, for the first quarter of the fiscal year under review, operating revenue totaled ¥625 million (vs. operating revenue of ¥284 million for the same quarter in the previous fiscal year) and operating income was ¥77 million (vs. operating loss of ¥81 million for the same quarter in the previous fiscal year), primarily reflecting milestone revenue of US$5 million (received upon the enrollment of the first participants in the Phase 2b clinical trial for chronic stroke in the US) and proceeds from development support fee related to the joint development and license agreements concluded with Sumitomo Dainippon Pharma Co., Ltd. in North America. Ordinary loss was ¥320 million (vs. ordinary loss of ¥154 million for the same quarter in the previous fiscal year) and net loss attributable to owners of parent was ¥277 million (vs. net loss attributable to owners of parent of ¥109 million for the same quarter in the previous fiscal year), due to the recording of ¥7 million of interest expenses and ¥364 million of foreign exchange losses.

The Group consists of a single business segment, regenerative cell therapy using modified allogeneic stem cells; therefore, description of business performance by segment is omitted.

(2) Explanation of Financial Position

(Current assets)

The balance of current assets at the end of the first quarter of the fiscal year under review was ¥7,587 million, a decrease of ¥604 million compared to the end of the previous fiscal year (¥8,191 million), mainly due to a decrease of ¥618 million in cash and deposits.

(Non-current assets)

The balance of non-current assets at the end of the first quarter of the fiscal year under review was ¥73 million, a decrease of ¥6 million compared to the end of the previous fiscal year (¥79 million), mainly due to a decrease of ¥6 million in property, plant and equipment.

(Current liabilities)

The balance of current liabilities at the end of the first quarter of the fiscal year under review was ¥1,120 million, a decrease of ¥298 million compared to the end of the previous fiscal year (¥1,419 million), mainly due to a decrease of ¥200 million in current portion of long-term loans payable.

(Non-current liabilities)

The balance of non-current liabilities at the end of the first quarter of the fiscal year under review was ¥425 million, a decrease of ¥58 million compared to the end of the previous fiscal year (¥484 million), mainly due to a decrease of ¥58 million in deferred tax liabilities.

(Net assets)

Total net assets at the end of the first quarter of the fiscal year under review were ¥6,113 million (¥6,366 million at the end of the previous fiscal year), mainly due to the recording of ¥277 million in net loss attributable to owners of parent.

(3) Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information

No revisions have been made to the consolidated financial results forecasts for the first half and the full year of the fiscal year under review, as released on March 16, 2016.

2. Matters Concerning Summary Information (Notes)

(1) Changes in Significant Subsidiaries during the Three Months Ended April 30, 2016

There is no relevant information.

(2) Accounting Policies Adopted Specially for the Preparation of Quarterly Consolidated Financial Statements

There is no relevant information.

(3) Changes in Accounting Policies, Changes in Accounting Estimates and Retrospective Restatement

(Adoption of accounting standards for business combinations)

Effective from the first quarter of the fiscal year under review, the Company has adopted the "Revised Accounting Standard for Business Combinations" (Accounting Standards Board of Japan ("ASBJ") Statement No. 21, September 13, 2013), "Revised Accounting Standard for Consolidated Financial Statements" (ASBJ Statement No. 22, September 13, 2013) and "Revised Accounting Standard for Business Divestitures" (ASBJ Statement No. 7, September 13, 2013). Consequently, the Company has changed the presentation of net income and other items, and minority interests have been changed to non-controlling interests. To reflect the changes in presentation, quarterly consolidated financial statements for the first quarter of the previous fiscal year and consolidated financial statements for the previous fiscal year have been reclassified.

3. Significant Events Concerning Going Concern Assumption

There is no relevant information.

4. Quarterly Consolidated Financial Statements

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2016	As of April 30, 2016
Assets		
Current assets		
Cash and deposits	7,733,892	7,115,814
Other	457,599	471,409
Total current assets	8,191,492	7,587,223
Non-current assets		
Property, plant and equipment	67,974	61,914
Intangible assets	207	169
Investments and other assets	11,342	11,110
Total non-current assets	79,524	73,194
Total assets	8,271,017	7,660,417
Liabilities		
Current liabilities		
Short-term loans payable	100,000	100,000
Current portion of long-term loans payable	800,000	600,000
Provision for bonuses	20,994	38,917
Deferred tax liabilities	184,931	167,917
Other	313,651	213,811
Total current liabilities	1,419,577	1,120,646
Non-current liabilities		
Long-term loans payable	300,000	300,000
Deferred tax liabilities	184,931	125,938
Total non-current liabilities	484,931	425,938
Total liabilities	1,904,508	1,546,584
Net assets		
Shareholders' equity		
Capital stock	3,806,973	3,813,228
Capital surplus	7,518,415	7,524,670
Retained earnings	(4,978,932)	(5,256,334)
Treasury shares	(28)	(28)
Total shareholders' equity	6,346,428	6,081,535
Accumulated other comprehensive income		
Foreign currency translation adjustment	19,362	31,606
Total accumulated other comprehensive income	19,362	31,606
Subscription rights to shares	718	691
Total net assets	6,366,509	6,113,833
Total liabilities and net assets	8,271,017	7,660,417

(2) Quarterly Consolidated Statements of Income and Comprehensive Income

Quarterly Consolidated Statements of Income

For the Three Months Ended April 30

(Thousand yen)

	For the three months ended April 30, 2015	For the three months ended April 30, 2016
Operating revenue	284,698	625,598
Operating expenses		
Research and development expenses	205,984	366,964
Other selling, general and administrative expenses	160,264	181,414
Total operating expenses	366,249	548,378
Operating income (loss)	(81,550)	77,220
Non-operating income		
Interest income	47	4,109
Other	—	124
Total non-operating income	47	4,234
Non-operating expenses		
Interest expenses	4,468	7,143
Foreign exchange losses	17,736	364,427
Share issuance cost	32,446	—
Listing-related expenses	18,356	—
Financing expenses	—	30,000
Total non-operating expenses	73,007	401,570
Ordinary loss	(154,509)	(320,115)
Loss before income taxes	(154,509)	(320,115)
Income taxes - current	278	371
Income taxes - deferred	(45,712)	(43,084)
Total income taxes	(45,434)	(42,713)
Net loss	(109,075)	(277,402)
Net loss attributable to owners of parent	(109,075)	(277,402)

Quarterly Consolidated Statements of Comprehensive Income

For the Three Months Ended April 30

(Thousand yen)

	For the three months ended April 30, 2015	For the three months ended April 30, 2016
Net loss	(109,075)	(277,402)
Other comprehensive income		
Foreign currency translation adjustment	1,685	12,244
Total other comprehensive income	1,685	12,244
Comprehensive income	(107,389)	(265,157)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(107,389)	(265,157)
Comprehensive income attributable to non-controlling interests	—	—

(3) Notes to the Quarterly Consolidated Financial Statements

(Notes on going concern assumption)

There is no relevant information.

(Notes in the case of significant changes in shareholders' equity)

There is no relevant information.

(Segment information)

<Segment information>

I For the three months ended April 30, 2015 (from February 1, 2015 to April 30, 2015)

Segment information is omitted as the Group consists of a single business segment: regenerative cell treatment using modified allogeneic stem cells.

II For the three months ended April 30, 2016 (from February 1, 2016 to April 30, 2016)

Segment information is omitted as the Group consists of a single business segment: regenerative cell treatment using modified allogeneic stem cells.